NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

CHRISTINE JANKOWSKI, et al.,

Plaintiffs,

v.

ZYDUS PHARMACEUTICALS USA, INC. and DOES 1-50, Inclusive,

Defendants.

Civil Action No. 20-2458 (MAS) (TJB)

MEMORANDUM OPINION

SHIPP, District Judge

This matter comes before the Court upon Defendant Zydus Pharmaceuticals USA, Inc.'s ("Zydus" or "Defendant") Motion to Dismiss the First Amended Complaint. (ECF No. 11.) Plaintiffs[1] opposed (ECF No. 17) and Zydus replied (ECF No. 19).[2] The Court has carefully considered the parties' submissions and decides the matter without oral argument pursuant to Local Civil Rule 78.1. For the reasons set forth below, Defendants' Motion to Dismiss is granted.

[1] Plaintiffs are 209 individuals who either ingested Amiodarone or are the family members of individuals who died from or were injured by the drug after being diagnosed with atrial fibrillation. (First Am. Compl. ¶¶ 1-151(a) ("FAC"), ECF No. 8.)

[2] On December 30, 2020, this action was consolidated with Case No. 3:20-cv-13439-MAS-TJB (the "*Vining* action"). (ECF No. 23.) In their Joint Stipulation regarding case consolidation, the parties agreed that consolidating the two actions does not render the present motion to dismiss moot and that the same arguments asserted in Defendant's motion to dismiss, Plaintiffs' opposition, and Defendant's reply shall apply with equal force and effect to the plaintiffs in the *Vining* action. (Joint Stip. Regarding Case Consol. and Def.'s Mot. to Dismiss ¶¶ 1, 7, 8, 10, ECF No. 23.)

I. BACKGROUND

Zydus manufactures and sells Amiodarone, which is the generic form of Cordarone, a brand-name drug manufactured by Wyeth Pharmaceuticals, Inc. ("Wyeth"). Wyeth received approval from the Food and Drug Administration ("FDA") to market and sell Cordarone as a "drug of last resort for patients suffering from documented, recurrent, life threatening ventricular fibrillation and ventricular tachycardia." (FAC ¶ 166.) As a drug of last resort, the FDA approved its use only for individuals facing probable death and whose conditions would not respond to other available anti-arrhythmic drugs and therapies. (*Id.*)

Pursuant to the Hatch-Waxman Act of 1984, which amended the Food, Drug, and Cosmetic Act ("FDCA"), a generic manufacturer—like Zydus—is not required to repeat the FDA approval process undertaken by brand-name manufacturers. (*Id.* ¶ 162.) Instead, generic pharmaceutical manufacturers must submit an Abbreviated New Drug Application ("ANDA") to the FDA to obtain approval to manufacture a generic pharmaceutical following the FDA's approval of its brand-name equivalent. (*Id.*) The FDA approved Zydus's ANDA on March 30, 2001. (*Id.* ¶ 176 n.14.)

Plaintiffs allege that Wyeth aggressively and successfully marketed Cordarone for inappropriate "off-label" use as a "first line anti-arrhythmic therapy." (*Id.* ¶ 167.) An "off-label" use of a pharmaceutical occurs when it is used in a manner that has not been approved by the FDA. (*Id.*) According to Plaintiffs, the FDA repeatedly warned Wyeth to stop marketing Cordarone in a manner which downplayed its safety risks and promoted its off-label use. (*Id.*) Plaintiffs allege that as a result of Wyeth's pervasive and effective marketing activities, physicians did not appreciate the risks associated with Amiodarone and began to prescribe the drug as a first-line therapy for atrial fibrillation. (*Id.*) Plaintiffs allege that Defendant and other generic manufacturers "took

advantage of Wyeth's marketing plan positioning Amiodarone as a 'first line anti-arrhythmic' . . . and directly benefited from the decades of marketing of the drug for 'off-label' uses by Wyeth." (*Id.*) The FDA also promulgated a regulation requiring manufacturers of Amiodarone to make available to distributors a medication guide ("Medication Guide") setting forth in plain terms the drug's medical uses and health risks. (*Id.* ¶ 179; *see* 21 C.F.R. § 208.24 (2020).)

According to Plaintiffs, Zydus failed to provide, or make available for distribution, the FDA-required Medication Guide to both distributors and patients. Plaintiffs further allege Zydus took advantage of Wyeth's promotional marketing of the drug for off-label use, and failed to inform physicians, distributors, or patients of the many potential dangers of Amiodarone, including that it was not intended for use as a first-line therapy for atrial fibrillation. (*Id.* ¶ 167.)

Plaintiffs assert claims for: (1) strict products liability for failure to warn; (2) negligent failure to warn; (3) negligent off-label marketing and sale of Amiodarone for treatment of atrial fibrillation; (4) negligence per se; (5) strict liability for manufacturing defect; (6) fraud and deceit; and (7) wrongful death.

II. LEGAL STANDARD

District courts undertake a three-part analysis when considering a motion to dismiss pursuant to Federal Rule of Civil Procedure 12(b)(6). *Malleus v. George*, 641 F.3d 560, 563 (3d Cir. 2011). "First, the court must 'tak[e] note of the elements a plaintiff must plead to state a claim.'" *Id.* (quoting *Ashcroft v. Iqbal*, 556 U.S. 662, 675 (2009)) (alteration in original). Second, the court must accept as true all of the plaintiff's well-pled factual allegations and "construe the complaint in the light most favorable to the plaintiff." *Fowler v. UPMC Shadyside*, 578 F.3d 203, 210 (3d Cir. 2009) (quotation omitted). In doing so, the court is free to ignore legal conclusions or factually unsupported accusations that merely state "the-defendant-unlawfully-harmed-me."

Iqbal, 556 U.S. at 678 (citing *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007)). "[M]ere restatements of the elements of [a] claim[] . . . are not entitled to the assumption of truth." *Burtch v. Milberg Factors, Inc.*, 662 F.3d 212, 224 (3d Cir. 2011) (alterations in original) (quotation omitted). Finally, the court must determine whether "the facts alleged in the complaint are sufficient to show that the plaintiff has a 'plausible claim for relief.'" *Fowler*, 578 F.3d at 211 (quoting *Iqbal*, 556 U.S. at 679). "The defendant bears the burden of showing that no claim has been presented." *Hedges v. United States*, 404 F.3d 744, 750 (3d Cir. 2005) (citation omitted).

"Rule 12 prohibits the court from considering matters outside the pleadings in ruling on a motion to dismiss for failure to state a claim . . . and a court's consideration of matters outside the pleadings converts the motion to a motion for summary judgment." *Kimbugwe v. United States*, No. 12-7940, 2014 WL 6667959, at *3 (D.N.J. Nov. 24, 2014). "[A]n exception to the general rule is that a document integral to or explicitly relied upon in the complaint may be considered without converting the motion to dismiss into one for summary judgment." *In re Burlington Coat Factory Secs. Litig.*, 114 F.3d 1410, 1426 (3d Cir. 1997) (emphasis omitted) (internal quotation marks omitted). Notwithstanding these principles, courts may not consider claims raised for the first time in a plaintiff's opposition to a motion to dismiss. *See Pennsylvania ex rel. Zimmerman v. PepsiCo, Inc.*, 836 F.2d 173, 181 (3d Cir. 1988) ("[I]t is axiomatic that the complaint may not be amended by the briefs in opposition to a motion to dismiss." (internal quotation omitted)).

III. DISCUSSION

Defendant moves to dismiss Plaintiffs' claims on preemption grounds and for failure to state a claim. "The doctrine of preemption has constitutional roots in the Supremacy Clause," which provides that federal law is "supreme." *Sikkelee v. Precision Airmotive Corp.*, 907 F.3d 701, 709 (3d Cir. 2018) (second quotation quoting U.S. Const. art. VI, cl. 2). While there is no express

preemption clause in the FDCA that applies to prescription drugs, *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 327 (2008), the FDCA may impliedly preempt a drug product liability claim. *Wyeth v. Levine*, 555 U.S. 555, 568, 573 (2009). It is true that there is a presumption against preemption in areas that are traditionally within the states' police powers, such as health and safety. *Bruesewitz v. Wyeth Inc.*, 561 F.3d 233, 240 (3d Cir. 2009). Yet a state law claim that "stands as an obstacle to Congressional objectives" will be preempted. *Id.* at 239. And, similarly, a state law claim will be preempted if it is "impossible for a private party to comply with both state and federal requirements." *Mut. Pharm. Co. v. Bartlett*, 570 U.S. 472, 480 (2013) (citation omitted).

"Impossibility" preemption issues arise with some regularity in litigation asserting state-law tort claims against prescription-drug manufacturers. In *Wyeth v. Levine*, the Court held that a state-law failure-to-warn claim against a brand-name drug manufacturer was not preempted because FDA regulations allow those manufacturers to change labels without immediate agency approval. 555 U.S. at 568. *Wyeth*, which involved a branded drug, left unaddressed the case of a generic drug, which is subject to a different regulatory regime. "Under federal law, a generic drug manufacturer may produce a drug that is identical to one made by a brand-name manufacturer, but when it receives permission to do so, it must use the same FDA-approved design and warning labels as the brand-name manufacturer." *Sikkelee*, 907 F.3d at 712. Unlike brand-name manufacturers, then, a generic manufacturer cannot unilaterally change its label consistent with federal law. *Id.* In *PLIVA, Inc. v. Mensing*, which dealt with a generic pharmaceutical, the Court distinguished *Wyeth* and explained that "[t]he question for 'impossibility' is whether the private party could *independently* do under federal law what state law requires of it." *PLIVA, Inc. v. Mensing*, 564 U.S. 604, 620 (2011) (emphasis added). "[W]hen a party cannot satisfy its state

duties without the Federal Government's special permission and assistance, . . . that party cannot independently satisfy those state duties for pre-emption purposes." *Id.* at 623–24.

And finally, "when a plaintiff's claims 'exist solely by virtue of the FDCA['s] . . . requirements,' state law claims are impliedly preempted." *Frei v. Taro Pharm. U.S.A., Inc.*, 443 F. Supp. 3d 456, 468 (S.D.N.Y. 2020) (quoting *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 352 (2001)). Courts must, therefore, analyze "whether there is an underlying state tort duty and make the preemption decision based on the existence or absence of this duty." *Polt v. Sandoz, Inc.*, 462 F. Supp. 3d 557, 565 (E.D. Pa. 2020). "Except in circumstances not relevant here, 'all such proceedings for the enforcement, or to restrain violations, of [the FDCA] shall be by and in the name of the United States.'" *McDaniel v. Upsher-Smith Labs., Inc.*, 893 F.3d 941, 944 (6th Cir. 2018) (quoting 21 U.S.C. § 337(a)). "The FDCA leaves no doubt that it is the Federal Government rather than private litigants who are authorized to file suit for noncompliance . . . ." *Buckman*, 531 U.S. at 349 n.4. "[T]he FDCA does not provide a private right of action for a defendant's violation of its provisions." *Frei*, 443 F. Supp. 3d at 468 (citing *Merrell Dow Pharm. Inc. v. Thompson*, 478 U.S. 804, 810 (1986)).

A. Failure to Warn and Failure to Include Medication Guide Claims

Plaintiffs plead failure to warn claims under strict liability and negligence theories. Zydus argues that any state law failure to warn claims that would have required Zydus to alter its product or labeling are preempted. (Def.'s Moving Br. 24–26, ECF No. 12.) Plaintiffs argue that because they only allege that Defendants did not provide FDA labeling, their claims are not preempted. (Pls.' Opp'n Br. 21, ECF No. 17.)

The FDA regulation titled "Distributing and dispensing a Medication Guide," provides in pertinent part:

> Each manufacturer who ships a container of drug product for which a Medication Guide is required . . . is responsible for ensuring that Medication Guides are available for distribution to patients by either:
>
> (1) Providing Medication Guides in sufficient numbers to distributors, packers, or authorized dispensers to permit the authorized dispenser to provide a Medication Guide to each patient receiving a prescription for the drug product; or
>
> (2) Providing the means to produce Medication Guides in sufficient numbers to distributors, packers, or authorized dispensers to permit the authorized dispenser to provide a Medication Guide to each patient by receiving a prescription for the drug product.

21 C.F.R. § 208.24(b). The regulation further states:

> Each authorized dispenser of a prescription drug product for which a Medication Guide is required . . . shall, when the product is dispensed to a patient (or to a patient's agent), provide a Medication Guide directly to each patient (or to the patient's agent).

21 C.F.R. § 208.24(e).

Accordingly, the regulatory text obligates manufacturers to provide the Medication Guide in sufficient numbers, or the means to produce them in sufficient numbers, to distributors, so that such distributors could in turn provide the Medication Guide to patients.

The *Frei* court's analysis is illustrative here. *Frei*, 443 F. Supp. 3d 456. That case dealt with another generic manufacturer of Amiodarone with nearly identical claims alleged. There, the court found that "[a]lthough plaintiffs couch their failure to warn claims in traditional state tort law, it is clear the existence of the FDA's [M]edication [G]uide regulation is the gravamen of these claims. There is no question [generic manufacturer defendant's] [A]miodarone [M]edication [G]uide is a 'critical element' in this case." *Frei*, 443 F. Supp. 3d at 468 (citing *McDaniel*, 893 F.3d at 944). In *Frei*, the court found that the plaintiffs did not identify a parallel state law requiring defendant to make available to distributors an Amiodarone Medication Guide. *Id.*

Similarly, here, Plaintiffs do not identify a parallel state law requiring Zydus to make available to distributors an Amiodarone Medication Guide. Plaintiffs allege that "[f]ailure by

Defendants to provide the Medication Guide and ensure its distribution in accordance with the requirements applicable to Defendants results in the distribution of a mislabeled drug, which is in violation of New Jersey state law." (FAC ¶ 179; *see id.* ¶ 180 (citing N.J. Stat. Ann. § 24:5-18(f) ("[A] drug . . . shall also be deemed to be misbranded [u]nless its labeling bears (1) adequate directions for use; and (2) such adequate warnings against use . . . where its use may be dangerous to health")).) Plaintiffs also argue that "the *duty* to warn comes from state law [and] Plaintiffs alleged Defendant did not adequately warn under state law because it did not follow the regulations." (Pls.' Opp'n Br. 14-15 (citing FAC ¶¶ 1-151(e) ("Medication Guides were not provided by Zydus . . . to pharmacists for distribution . . . in sufficient quantities, if at all. Plaintiff received and ingested a mislabeled drug under NJ state law.")).) Here, Plaintiffs conflate a failure to provide the Medication Guide in sufficient numbers with mislabeling of a drug, in an attempt to "couch their failure to warn claims in traditional state tort law." *Frei*, 443 F. Supp. 3d at 468. Plaintiffs are arguing that the Medication Guide was not distributed in accordance with the FDA regulations, but do not cite to a parallel state law that requires distribution of the Medication Guide. Plaintiffs' failure to warn claims against Zydus are therefore preempted inasmuch as they concern Zydus's alleged failure to provide the Medication Guide to Amiodarone distributors and patients.

B. Manufacturing Defect Claim

Plaintiffs' manufacturing defect claims are preempted for similar reasons. Once again, "it is clear the existence of the FDA's [M]edication [G]uide regulation is the gravamen of these claims." *Frei*, 443 F. Supp. 3d at 468. Plaintiffs allege "Defendant failed to comply with the FDA's Good Manufacturing Practice for Finished Pharmaceuticals." (FAC ¶ 285 (citing 21 C.F.R § 211).) Plaintiffs allege that pursuant to this provision, "[l]abeling that does not meet the required specifications must be rejected and only drugs containing labeling and packaging meeting written

specifications shall be distributed," and that the Medication Guide "is part of Amiodarone's labeling." (FAC ¶¶ 286, 289.) Plaintiffs further allege that "Defendant also failed to implement a safer alternative design for the delivery of the Medication Guide . . . ." (*Id.* ¶ 288.) Plaintiffs allege that these failures regarding the "manufacture, processing, packing or holding of a drug renders the drug adulterated under" the FDCA and New Jersey state law. (*Id.* ¶¶ 291-92 (citing N.J. Stat. Ann. § 24:5-10(e) ("a drug . . . shall be deemed adulterated [i]f it is dangerous to health when used in the dosage, or with the frequency or duration prescribed, recommended, or suggested in the labeling thereof.").)

First, Plaintiffs' allegations here do not sound in defective manufacturing and may be dismissed on that basis. Moreover, Plaintiffs fail to assert a parallel state law claim. Here, the New Jersey law regarding adulterated drugs explicitly contemplates that a drug shall be deemed adulterated "when used . . . [as] suggested in the labeling thereof." N.J. Stat. Ann. § 24:5-10(e). As Plaintiffs acknowledge, however, Plaintiffs do not, and could not, "seek a label change." (Pls.' Opp'n Br. 21); *see, e.g.*, *Wagner v. Teva Pharm. USA, Inc.*, 840 F. 3d 355, 358 (7th Cir. 2016) ("[F]ederal law preempts state tort laws when the generic drug manufacturer could not have abided by this duty without . . . changing the drug's label.") To the extent Plaintiffs plausibly allege a claim for manufacturing defect, Plaintiffs' claim is preempted.

C. Failure to Report Adverse Events to the FDA

As an initial matter, the Court notes that "[i]n states that recognize failure to report claims, . . . a manufacturer's failure to report adverse events to the FDA can form the basis of a parallel claim that survives preemption." *In re Allergan Biocell Textured Breast Implant Prods. Liab. Litig.*, No. 19-2921, 2021 WL 1050910, at *11 (D.N.J. Mar. 19, 2021) (quoting *Nunn v. Mentor Worldwide, LLC*, No. 19-56391, 2021 WL 406304, at *3 (9th Cir. Feb. 5, 2021)). Nevertheless,

New Jersey is a jurisdiction that "declin[es] to recognize a separate state law duty to warn the FDA." *Id.* at *30 (citing *D'Addario v. Johnson & Johnson*, No. 19-15627, 2020 WL 3546750, at *4-5 (D.N.J. June 30, 2020)). Accordingly, Plaintiffs' allegation that Defendant failed to appropriately report adverse events to the FDA fails as a matter of law.

Moreover, the Court agrees that Plaintiffs have only "speculatively allege[d] that Zydus failed to report adverse events to the FDA." (*See* Def.'s Moving Br. 3–4.) Plaintiffs allege that "[t]here are millions o[f] persons who are diagnosed with [atrial fibrillation] annually" and that because Amiodarone "has become the number one prescribed drug for the treatment of" atrial fibrillation, "[b]ased on the percentages of persons diagnosed just with pulmonary toxicity, there would be tens of thousands o[f] adverse event reports submitted each year." (FAC ¶ 214.) Plaintiffs allege "that does not appear to be even close to the number of these reports submitted to the FDA." (*Id.*) Plaintiffs also allege that "[t]he number of [adverse events] reported" on the FDA's Adverse Event Reporting System "has increased significantly in the last few years for Amiodarone, correlating to the litigation surrounding Amiodarone which began in 2015." (*Id.* ¶ 219.) By way of example, Plaintiffs allege that there was a "270% increase" in the number of adverse events reported between 2014 and 2018. (*Id.*) Plaintiffs allege that this increase "indicates either underreporting" of adverse events or "that there has been a three-fold increase in the number of Amiodarone prescriptions" in those years. (*Id.*) Because Plaintiffs "fail to allege actual adverse events that [Zydus] did not report to the FDA," the Court finds that Plaintiffs' "conclusory and speculative allegations are insufficient to state a parallel failure to warn claim." *Nunn*, 2021 WL 406304, at *2 (citing *Twombly*, 550 U.S. at 555).

D. Negligent Marketing and Sale for Off-label Purpose

Zydus also argues any claims regarding its alleged promotion of Amiodarone for off-label use must be dismissed. Zydus argues that these causes of action are also impliedly preempted under 21 U.S.C. § 337(a)'s prohibition on private enforcement of the FDCA and its regulations, as recognized in *Buckman*. (Def.'s Moving Br. 23.)

The bases for Plaintiffs' claims are that Zydus took advantage of Wyeth's pervasive marketing of Amiodarone by marketing, selling, and distributing the drug as a first-line therapy for atrial fibrillation without the required Medication Guide and failed to correct information appearing in third-party prescribing reference sources, upon which many doctors allegedly rely. (FAC ¶¶ 275, 300.) Plaintiffs assert that Zydus was "under a duty to *correct these materials as* [a] *form of labelling.*" (*Id.* (emphasis added).)

To the extent Plaintiffs' claims are based on the content of the Medication Guide and information about off-label use of Amiodarone in these medical references, the claims are preempted under *Mensing*. As the Court explained in *Mutual Pharmaceutical Co. v. Bartlett*, 570 U.S. 472 (2013), *Mensing* "held that state failure-to-warn claims [against generic manufacturers] were pre-empted by the FDCA because it was impossible for drug manufacturers like [the defendant in Mensing] to comply with both the state-law duty to label their products in a way that rendered them reasonably safe and the federal-law duty not to change their drugs' labels." *Id.* at 488 (citing *Mensing*, 564 U.S. at 617–19). Plaintiffs allege in their Complaint that the Medication Guide and the information provided about Amiodarone in the third-party reference sources constitute labeling. (FAC ¶ 275.) These claims, accordingly, are preempted under *Mensing*.

As discussed above, Plaintiffs argue that they "do not seek a label change." (Pls.' Opp'n Br. 21.) But this assertion cannot be squared with Plaintiffs' allegations that Zydus's failure to report adverse events constituted a failure to warn. That allegation, if proven to be true, necessarily means that the warnings in the Medication Guide, and in the third-party reference sources—warnings that Plaintiffs themselves define as constituting labeling—were inadequate because they did not reflect adverse events. "If a claim depends on an allegation of inadequate labelling, it does seek a label change and it is preempted under *Mensing*." *Bennett v. Teva Pharms USA, Inc.*, 19-2126, 2021 WL 797834, at *4 (D. Del. Mar. 2, 2021) (finding similar claims against different Amiodarone generic manufacturer preempted by *Mensing*).

E. Negligence Per Se

"[T]he doctrine of per se liability does not create an independent basis of tort liability but rather establishes, by reference to a statutory scheme, the standard of care appropriate to the underlying tort." *In re Orthopedic Bone Screw Prods. Liab. Litig.*, 193 F.3d 781, 790 (3d Cir. 1999) (citing *Grove Fresh Distribs., Inc. v. Flavor Fresh Foods, Inc.*, 720 F. Supp. 714, 716 (N.D. Ill. 1989)). And while "the FDCA or its accompanying regulations" can be invoked to "establish the standard or duty which defendants allegedly failed to meet," *id.* (citation omitted), Plaintiffs have failed to do so here.

Here, Plaintiffs' negligence per se claim is premised on Zydus's "failure to ensure the Medication Guide was provided to Plaintiffs with prescriptions of Amiodarone, and to additionally provide adequate warnings regarding the unapproved 'off-label' use of Amiodarone for the treatment of [atrial fibrillation]." (FAC ¶ 282). Plaintiffs again make nearly identical allegations as raised in *Frei*. The *Frei* court found that "[a]side from the federal [M]edication [G]uide regulation—which is not privately enforceable and, on its face, contains no duty on the part of

manufacturers to provide [M]edication [G]uides directly to patients," the plaintiffs in that case alleged violation of a New York law that made it a misdemeanor to "misbrand any drug" or to manufacture or sell "adulterated or misbranded" drugs. *Frei*, 443 F. Supp. 3d at 469. The court found that plaintiffs failed to plausibly plead that the generic manufacturer defendant had taken part in any of the state law's proscribed conduct. *Id.* As discussed above, the similar state laws invoked by Plaintiffs here fail for the same reasons.

Additionally, to the extent Plaintiffs' complaint can be understood as alleging the warnings for Amiodarone were inadequate, despite their argument that they do not make that claim, the FDA approved the labeling and warning information associated with Cordarone/Amiodarone. Zydus, a generic pharmaceutical manufacturer, therefore, has an ongoing duty to provide the same warning labels and information distribution as those of the brand-name manufacturer. Zydus "is precluded under federal law from unilaterally altering such information." *Id.* For these reasons, Plaintiffs' negligence per se claim is dismissed.

F. Fraud

"To the extent that claims sound in fraud or misrepresentation, they 'must state with particularity the circumstances constituting the fraud.'" *Francis E. Parker Mem'l Home, Inc. v. Georgia-Pacific LLC*, 945 F. Supp. 2d 543, 551 (D.N.J. 2013) (citing Fed. R. Civ. P. 9(b)). Zydus argues Plaintiffs fail to allege fraud or misrepresentation with particularity, as required by Rule 9(b). (Def.'s Moving Br. 33.)

Here, Plaintiffs allege Zydus failed to report all adverse events to the medical community through the FDA's Adverse Event Reporting System. (FAC ¶¶ 298–99.) Plaintiffs also allege Zydus "provided or failed to correct false and misleading information about the indications and uses of Amiodarone provided to physicians via reference materials," which are used by physicians

in prescribing situations and which the prescribing physicians read and rely on in prescribing Amiodarone to Plaintiffs. (*Id.* ¶ 300.) Plaintiffs allege that "Zydus either was or should have been aware" of the allegedly misleading information in these third-party reference materials because, "for example, Zydus permitted use of pictures of [its] own Amiodarone pills" in one of these third-party references. (*Id.* ¶ 252.)

Although Plaintiffs claim Zydus failed to correct false and misleading information about Amiodarone provided to physicians in third-party reference materials, "[P]laintiffs do not connect these general allegations to their alleged personal injuries." *Frei*, 443 F. Supp. 3d at 471. Moreover, Plaintiffs do not allege specific or sufficient facts concerning *Zydus's* marketing and promotional activities. Plaintiffs have, accordingly, failed to sufficiently plead plausible fraud claims by not stating with "particularity the circumstances constituting the fraud." *Francis*, 945 F. Supp. 2d at 551; Fed. R. Civ. P. 9(b). Plaintiffs' fraud claims are therefore dismissed.

IV. CONCLUSION

For the reasons set forth above, the Court grants Defendants' Motion to Dismiss.[3] The Amended Complaint is dismissed without prejudice. The Court will provide Plaintiffs one final opportunity to amend their pleading and will set forth a deadline to file a second amended complaint in the accompanying order.

MICHAEL A. SHIPP
UNITED STATES DISTRICT JUDGE

[3] As Plaintiffs acknowledge, "their wrongful death claims are premised on their other claims." (Pls.' Opp'n Br. 32.) Accordingly, because Defendant's motion to dismiss is granted as to all of Plaintiffs' other claims, this derivative claim fails.